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Mail Stop Amendment
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On December 2, 2004

TOWNSEND and TOWNSEND and CREW LLP

By: 

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Nikhilesh N. Singh, et al.

Application No.: 10/763,641

Filed: January 22, 2004

For: METHODS AND COMPOSITIONS
FOR DELIVERING 5-HT₃
ANTAGONISTS ACROSS THE ORAL
MUCOSA

Examiner: To Be Assigned

Art Unit: 1615

INFORMATION DISCLOSURE
STATEMENT UNDER 37 CFR §1.97 and
§1.98

Mail Stop Amendment
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P.O. Box 1450
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Sir:

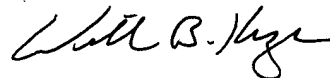
The references cited on the attached form PTO/SB/08A and PTO/SB/08B are being called to the attention of the Examiner. In accordance with the Office's waiver, issued in the August 5, 2003 Official Gazette, copies of the cited U.S. patent publications are not enclosed. Copies of all other references are submitted herewith. It is respectfully requested that the cited references be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom.

Also enclosed is a copy of the International Search Report issued in connection with the corresponding International Patent Application No. PCT/US04/01807.

As provided for by 37 CFR 1.97(g) and (h), no inference should be made that the information and references cited are prior art merely because they are in this statement and no representation is being made that a search has been conducted or that this statement encompasses all the possible relevant information.

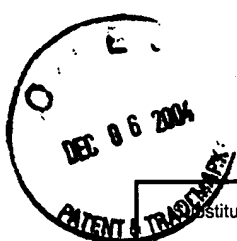
Applicant believes that no fee is required for submission of this statement. However, if a fee is required, the Commissioner is authorized to deduct such fee from the undersigned's Deposit Account No. 20-1430. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

Respectfully submitted,



William B. Kezer
Reg. No. 37,369

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, Eighth Floor
San Francisco, California 94111-3834
Tel: 925-472-5000
Fax: 925-472-8895
WBK:jvl
60318071 v1



INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Complete if Known	
		Application Number	10/763,641
		Filing Date	January 22, 2004
		First Named Inventor	Singh, Nikhilesh N.
		Art Unit	1615
		Examiner Name	To Be Assigned
Sheet 1	of 5	Attorney Docket Number	022205-000110US

U.S. PATENT DOCUMENTS+					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number Kind Code ² (if known)			
	1.	3,806,290	04-23-1974	Graff et al.	
	2.	4,151,270	04-24-1979	Ream et al.	
	3.	4,209,505	06-24-1980	Mikhail	
	4.	4,276,296	06-30-1981	Brown et al.	
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	38.	6,020,001	02-01-2000	Phillips et al.	
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	41.	6,110,486 A	08-29-2000	Dugger, III	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Complete if Known	
		Application Number	10/763,641
		Filing Date	January 22, 2004
		First Named Inventor	Singh, Nikhilesh N.
		Art Unit	1615
		Examiner Name	To Be Assigned
Sheet 2 of 5	Attorney Docket Number	022205-000110US	

U.S. PATENT DOCUMENTS+					
Examiner Initials*	Cite No. ¹	Document Number Number Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	42.	6,197,334	03-06-2001	Renda	
	43.	6,200,604 B1	03-13-2001	Pather et al.	
	44.	6,255,502	07-03-2001	Penkler et al.	
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	80.	2003/0091629 A1	05-15-2003	Pather et al.	
	81.	2003/0104041 A1	06-05-2003	Hsu et al.	
	82.	2003/0124184 A1	07-03-2003	Mezaache et al.	

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60318071 v1

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			Application Number	10/763,641	
			Filing Date	January 22, 2004	
			First Named Inventor	Singh, Nikhilesh N.	
			Art Unit	1615	
			Examiner Name	To Be Assigned	
Sheet	3	of	5	Attorney Docket Number	022205-000110US

U.S. PATENT DOCUMENTS+					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number Kind Code ² (if known)			
	83.	2003/0165566 A1	09-04-2003	O'Toole et al.	
	84.	2003/0185884 A1	10-02-2003	Singh et al.	
	85.	2003/0203022 A1	10-30-2003	Mizumoto et al.	

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Examiner Initials*	Cite No. ¹	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
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	86.	EP	0 433 043	A1	06-19-1991	Peirce Management		<input type="checkbox"/>
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	89.	WO	92/14708	A1	09-03-1992	Glaxo Group		<input type="checkbox"/>
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	94.	WO	00/13662	A2	03-16-2000	Henningfield		<input type="checkbox"/>
	95.	WO	00/66115	A1	11-09-2000	Glaxo Group		<input type="checkbox"/>
	96.	WO	00/67799	A1	11-16-2000	Dettmar		<input type="checkbox"/>
	97.	WO	01/39836	A1	06-07-2001	Natco Pharma Ltd.		<input type="checkbox"/>
	98.	WO	01/41749	A2	06-14-2001	Glaxo Grp. Ltd.		<input type="checkbox"/>
	99.	WO	01/89476	A1	11-29-2001	NPD LLC		<input type="checkbox"/>
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	101.	WO	02/102357	A1	12-27-2002	Olsson Roland		<input type="checkbox"/>
	102.	WO	03/039518	A1	05-15-2003	Adusumilli Prasad		<input type="checkbox"/>
	103.	WO	03/084515	A1	10-16-2003	Transoral Pharmaceuticals		<input type="checkbox"/>
	104.	WO	03/086343	A2	10-23-2003	Cadila Healthcare		<input type="checkbox"/>
	105.	WO	03/092591	A2	11-13-2003	NPD LLC		<input type="checkbox"/>
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				Application Number	10/763,641
				Filing Date	January 22, 2004
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				Art Unit	1615
				Examiner Name	To Be Assigned
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NON PATENT LITERATURE DOCUMENTS				
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		T ²
	106.	AUNGST, B.J., "Site-dependence and structure-effect relationships for alkylglycosides as transmucosal absorption promoters for insulin" Int. J. Pharm. 105:219-225 (1994).		
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	111.	GANDHI, R. and ROBINSON, J., "Mechanisms of penetration enhancement for transbuccal delivery of salicylic acid" Int. J. Pharm. 85:129-140 (1992).		
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	118.	LIEBERMAN, H.A. et al., (eds.), <u>Pharmaceuticals Dosage Forms: Tablets</u> Second Ed., Marcel Dekker, Inc., New York, NY, Vol. 1, pp.vii-x, Table of Contents only (1989).		
	119.	MANGANARO, A.M. and WERTZ, P.W., "The effects of permeabilizers on the in vitro penetration of propranolol through porcine buccal epithelium" Mil. Med. 161(11):669-672 (1996).		
	120.	NAKANE, S. et al., "Oramucosal delivery of LHRH: pharmacokinetic studies of controlled and enhanced transmucosal permeation" Pharmac. Devel. Techn. 1(3):251-259 (1996).		
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	122.	PATHER, S. et al., "Enhanced buccal delivery of fentanyl using the oravescent drug delivery system" Drug Delivery Technology 1(1):8 pages (2001).	
	123.	RATHBONE, M. et al., "The oral cavity as a site for systemic drug delivery" Adv. Drug Del. Rev. 13:1-22 (1994).	
	124.	SHOJAEI, A. et al., "Buccal Mucosa as a route for systemic drug delivery: a review" J. Pharm. Pharmaceut. Sci. 1(1):15-30 (1998).	
	125.	SIEGAL, I.A. and GORDON, H.P., "Effects of surfactants on the permeability of canine oral mucosa in vitro" Tox. Lett. 26:153-157 (1985).	
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	127.	STEWART, A. et al., "The effect of enhancers on the buccal absorption of hybrid (BDBB) α -interferon" Int. J. Pharm. 104:145-149 (1994).	
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TRANSMITTAL FORM

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Total Number of Pages in This Submission

12

Application Number

10/763,641

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First Named Inventor

Singh, Nikhilesh N.

Art Unit

1615

Examiner Name

To Be Assigned

Attorney Docket Number

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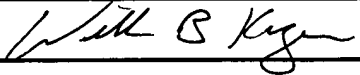
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Remarks

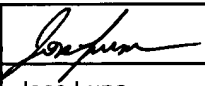
The Commissioner is authorized to charge any additional fees to Deposit Account 20-1430.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Townsend and Townsend and Crew LLP		
Signature			
Printed name	William B. Kezer		
Date	December <u>2</u> , 2004	Reg. No.	37,369

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